

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
 DORSEY & WHITNEY LLP
 Attn. Abelev, Gary
 250 Park Avenue
 New York NY 10177
 ETATS-UNIS D'AMERIQUE

Patent Mail Received

AUG 13 2008

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 189171/PCT	Date of mailing (day/month/year)	11/08/2008
International application No. PCT/US2008/058703	FOR FURTHER ACTION	See paragraphs 1 and 4 below
International filing date (day/month/year)	28/03/2008	

Applicant

THE GENERAL HOSPITAL CORPORATION

1. The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no International search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/AB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Norbert Hiesch
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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 189171/PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2008/058703	International filing date (day/month/year) 28/03/2008	(Earliest) Priority Date (day/month/year) 30/03/2007
Applicant THE GENERAL HOSPITAL CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International search report consists of a total of 5 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of:
 - the international application in the language in which it was filed
 - a translation of the international application into _____, which is the language of a translation furnished for the purposes of International search (Rules 12.3(a) and 23.1(b))
- b. This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).
- c. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.
- 2. Certain claims were found unsearchable (See Box No. II)
- 3. Unity of Invention is lacking (see Box No III)

4. With regard to the title,

- the text is approved as submitted by the applicant
- the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- the text is approved as submitted by the applicant
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 11A
 - as suggested by the applicant
 - as selected by this Authority, because the applicant failed to suggest a figure
 - as selected by this Authority, because this figure better characterizes the invention
- b. none of the figures is to be published with the abstract

4. CLASSIFICATION OF SUBJECT MATTER	INV. A61B1/00	A61B5/00	A61B19/00	G02B6/04
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G02B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 214 538 A (LOBB DANIEL R [GB]) 25 May 1993 (1993-05-25)	1-4, 6, 7, 11-13, 16, 17, 19, 20 5, 14, 15, 18
Y	column 1, line 55 - column 2, line 45 column 3, line 20 - column 8, line 52 -----	5, 14, 15, 18
Y	US 5 411 016 A (KUME STEWART M [US] ET AL) 2 May 1995 (1995-05-02) column 3, line 33 - column 7, line 38 figure 4 ----- -----	5, 14, 15, 18

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

24 July 2008

Date of mailing of the international search report

11/08/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl
Fax: (+31-70) 340-3016

Authorized officer

Montes, Pau

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	<p>DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; October 2007 (2007-10), "Abstracts of the 19th Annual Symposium of Transcatheter Cardiovascular Therapeutics, October 20-25, 2007, Washington, DC, USA." XPO02488653</p> <p>Database accession no. NLM18051250 abstract & THE AMERICAN JOURNAL OF CARDIOLOGY OCT 2007, vol. 100, no. 8 Suppl TCT2007, October 2007 (2007-10), pages 1L-235L, ISSN: 0002-9149</p> <p>& SEEMANTINI K. NADKARNI, DVIR YELIN, BRETT E. BOUMA, GUILLERMO J. TEARNEY: "Laser speckle imaging using optical fiber bundles: implications for the intravascular characterization of atherosclerotic plaque" TRANSCATHETER CARDIOVASCULAR THERAPEUTICS, October 2007 (2007-10); http://www.tct2007.com/</p> <p>-----</p>	1-4, 6-14, 16, 17, 19, 20
A	<p>EP 1 324 051 A (FORRESTER KEVIN R [CA]; TULIP JOHN [CA]; BRAY ROBERT C [CA]) 2 July 2003 (2003-07-02)</p> <p>paragraph [0010] - paragraph [0026] paragraph [0040] - paragraph [0046]</p> <p>-----</p>	1-20

INTERNATIONAL SEARCH REPORTinternational application No.
PCT/US2008/058703**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

Information on patent family members

PCT/US2008/058703

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 5214538	A	25-05-1993	NONE			
US 5411016	A	02-05-1995	US	7169140 B1		30-01-2007
EP 1324051	A	02-07-2003	NONE			

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2008/058703	International filing date (day/month/year) 28.03.2008	Priority date (day/month/year) 30.03.2007
International Patent Classification (IPC) or both national classification and IPC INV. A61B1/00 A61B5/00 A61B19/00 G02B6/04		
Applicant THE GENERAL HOSPITAL CORPORATION		
<p>1. This opinion contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application</p> <p>2. FURTHER ACTION</p> <p>If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>		

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx. 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Montes, Pau

Telephone No. +49 89 2399-7259



Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:
 - the international application in the language in which it was filed
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - on paper
 - in electronic form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in electronic form.
 - furnished subsequently to this Authority for the purposes of search.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- the entire international application
- claims Nos. 21

because:

- the said international application, or the said claims Nos. 21 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- no international search report has been established for the whole application or for said claims Nos. 21
- a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- See Supplemental Box for further details

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/058703

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>5, 8-10, 14-15, 18</u>
	No: Claims	<u>1-4, 6-7, 11-13, 16-17, 19-20</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-20</u>
Industrial applicability (IA)	Yes: Claims	<u>1-20</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Independent method claim 21 defines a method for analysing a tissue which encompasses intracoronary laser speckle imaging (see par. [0005] in the description). Intracoronary laser speckle imaging implicitly requires the step of introducing an imaging device into an artery. As a consequence, the method defined in claim 21 is considered as a method for the treatment of the human body by surgery and has therefore not been searched (Article 17(2)(a)(i) and Rule 39.1(iv) PCT) and no examination will be carried out in respect of independent claim 21 (Article 34(4)(a)(i) and Rules 66.1(e), 67.1(iv) PCT).

Re Item V.

1 Reference is made to the following documents:

D1: US-A-5 214 538 (LOBB DANIEL R [GB]) 25 May 1993 (1993-05-25)
D2: US-A-5 411 016 (KUME STEWART M [US] ET AL) 2 May 1995 (1995-05-02)
D3: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM),
BETHESDA, MD, US; October 2007 (2007-10), "Abstracts of the 19th Annual
Symposium of Transcatheter Cardiovascular Therapeutics, October 20-25, 2007,
Washington, DC, USA." XP002488653 Database accession no. NLM18051250

2 The subject-matter of claims 1-4, 6-7, 11-13, 16-17 and 19-20 appears not to be new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

2.1 Independent apparatus claim 1 appears not to be new over the disclosure of document D1. This document discloses (the references in parentheses applying to this document):

- an apparatus for analyzing tissue (see abstract), comprising:
- at least one first arrangement configured to illuminate at least one anatomical structure with at least one of at least one electro-magnetic radiation (see col. 3, l. 29-37); and
- at least one second arrangement that includes at least two wave-guiding

arrangements associated with one another that are configured to receive a further electro-magnetic radiation reflected from the tissue and transmit at least one speckle pattern associated with the further electro-magnetic radiation (see col. 3, l. 20-28 and col. 5, l. 40-48), wherein the wave-guiding arrangements are structured so as to reduce crosstalk therebetween (this sentence does not define any clear technical restriction since it merely describes a result to be achieved).

2.2 The additional features of dependent claims 2-4, 6-7, 11-13, 16-17 and 19-20 appear to be disclosed in document D1. The corresponding passages are the following:

- for claims 2-3 and 13: see col. 3, l. 58-65
- for claim 4: it is not clear what is meant by "one section of at least one of the wave-guiding arrangements". As a consequence, claim 4 does not define any clear technical restriction
- for claim 6: it is not clear what is meant by a "further" single fibre since there is no fibre defined in claim 1. This lack of clarity notwithstanding the subject-matter of claim 6 appears to be known from D1 (see col. 3, l. 32-37)
- for claim 7: in a fibre bundle, the wave-guiding arrangements are always separated by a predetermined distance. Furthermore, the fact that said distance is selected to reduce cross-talk does not define a clear technical restriction
- for claim 11: it is not clear what is meant by "a wave-guide that has an angle" (e.g. any optical fibre can be bent and forms therefore an angle with itself). Furthermore, "having a characteristic so as to reduce cross-talk" is not a technical feature since it merely describes a target to be achieved. As a consequence, claim 11 defines no clear technical restriction
- for claim 12: it is not clear how an arrangement can have a plurality of arrangements (e.g. a fibre having a plurality of

fibres?)

- for claims 16-17 and 19: the sentence "an arrangement is structured to be provided in a particular proximity to an anatomical structure" does not define any clear technical feature. Neither does the fact that said anatomical structure is a blood vessel.
- for claim 20: see abstract; the device disclosed in D1 is suitable for visualising the interior of blood vessels and therefore to transmit an angioscopy image

3 The subject-matter of dependent claims 5, 8-10, 14-15 and 18 is known from the prior art and does not therefore involve an inventive step in the sense of Article 33(3) PCT. The corresponding documents and passages are the following:

- for claim 5 and 14: see col. 6, l. 48-51 in D2
- for claim 8: it is well known in the art that increasing the distance between wave-guiding cores reduces cross-talk. The particular choice of a distance is therefore a mere design option which does not imply an inventive activity as in claim 9 it is not clear what is meant by "one section of at least one of the wave-guiding arrangements". Furthermore, the sentence "which has characteristics so as to reduce cross-talk" does not confer any technical restriction since it merely describes a result to be achieved. This lack of clarity notwithstanding, the subject-matter of claims 9 and 10 appears not to contribute an inventive step since wave-guiding arrangements (e.g. optic fibre) covered by a cladding material as well as wave-guiding bundles (e.g. optic fibre bundles) are well-known in the art
- for claim 15: see col. 5, l. 19-30 in D2; the use of a device to move an arrangement within a catheter is well-known in the

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2008/058703

art (e.g. accessory drive units)
- for claim 18: see col. 5, l. 7-18 in D2

4 The attention of the applicant is drawn to the fact that document D3 published after the priority date but before the filing date is considered to be very relevant for the examination of the present application. Said document has not been taken into account for the present examination since the validity of the priority document has not been checked.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

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